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## PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY **PCT** LAURA PEREIRA CATALYST LAW GROUP, APC 4330 LA JOLLA VILLAGE DRIVE, SUITE 220 WRITTEN OPINION OF THE SAN DIEGO, CA 92122 INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis. 1) Date of mailing U9 SEP 20115 (day/month/year) FOR FURTHER ACTION Applicant's or agent's file reference See paragraph 2 below 8024-014-WO International filing date (day/month/year) International application No. Priority date (day/month/year) 20 January 2004 (20.01.2004) PCT/US05/02017 20 January 2005 (20.01.2005) International Patent Classification (IPC) or both national classification and IPC IPC(7): A61K 31/55, 31/70 and US Cl.: 514/35, 36, 37, 38, 39, 40, 41, 212 Applicant OPTIMER PHARMACEUTICALS, INC. 1. This opinion contains indications relating to the following items: Box No. I Basis of the opinion Box No. II Priority Non-establishment of opinion with regard to novelty, inventive step and industrial applicability Box No. III Box No. IV Lack of unity of invention Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial Box No. V applicability; citations and explanations supporting such statement Box No. VI Certain documents cited Box No. VII Certain defects in the international application Box No. VIII Certain observations on the international application 2. FURTHER ACTION If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered. If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later. For further options, see Form PCT/ISA/220. 3. For further details, see notes to Form PCT/ISA/220. Name and mailing address of the ISA/ US Authorized office Mail Stop PCT, Attn: ISA/US James Wilso Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450

Telephone No. 703-308-1235

Facsimile No. (703) 305-3230 Form PCT/ISA/237 (cover sheet) (January 2004)

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/US05/02017

| Box No. I Basis of this opinion  |   |  |  |  |
|--|---|--|--|--|
|  |   |  |  |  |
| 1. With regard to the language, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.   |   |  |  |  |
|  | This opinion has been established on the basis of a translation from the original language into the following language, which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)). |  |  |  |
| 2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:  |   |  |  |  |
| a.   | type of material  |  |  |  |
|  | a sequence listing  |  |  |  |
|  | table(s) related to the sequence listing  |  |  |  |
| ъ.   | format of material  |  |  |  |
|  | in written format   |  |  |  |
|  | in computer readable form   |  |  |  |
| c.   | time of filing/furnishing   |  |  |  |
|  | contained in international application as filed.  |  |  |  |
|  | filed together with the international application in computer readable form.  |  |  |  |
|  | furnished subsequently to this Authority for the purposes of search.  |  |  |  |
|  |   |  |  |  |
| 3. In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished. |   |  |  |  |
| 4. Additional comments:  |   |  |  |  |
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| n  | //SA/237/Roy No. D (Ignuage 2004)   |  |  |  |

## WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

International application No. PCT/US05/02017

| Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement   |   |  |  |  |
|---|---|--|--|--|
| 1. Statement  |   |  |  |  |
| Novelty (N)   | Claims 2, 19, 37, 38 and 40   | YES  |  |  |
| norony (ny  | Claims 1, 3-18, 20-36, 39 and 41  |  |  |  |
| Inventive step (IS)   | Claims 2, 19, 37, 38 and 40   | YES  |  |  |
| mionare stop (18)   | Claims 1, 3-18, 20-36, 39 and 41  |  |  |  |
| Industrial applicability (IA)   | Claims <u>1-41</u>  | YES  |  |  |
| industrial approaching (i.e.)   | Claims NONE   | NO   |  |  |
| al disclose the treatment of prediabetes a glycosidas as set forth in claim 2 and prevention of inflammate Liu et al also disclose a pharmaceutical composition 38 and 40.  Claims 1, 3-18, 20-36, 39 and 41 the criteria set out claimed methods and compositions. | Article 33(2) as being anticipated by Liu et al (U.S. Patent se inhibitor (column 4, lines 30-34). Prevention of degenera by condition as set forth in claim 19 would have been inheren comprising a glycosidase inhibitor (column 5, lines 10-30) at in PCT Article 33(2)-(3), because the prior art does not tead at 33(4), and thus meet industrial applicability because the su | tive cartilage condition<br>ent from such treatment.<br>as set forth in claims 37,<br>ch or fairly suggest the |  |  |

Form PCT/ISA/237 (Box No. V) (January 2004)